AMERICAN HOLISTIC VETERINARY MEDICAL ASSOCIATION
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July 10, 2002

Dr. Sharon Benz
Nutrition and Labeling Team
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place, HFV-228
Rockville, MD 20855

Subject: **POSITION STATEMENT ON REGULATION OF NUTRACEUTICALAND HERBAL PRODUCTS FOR ANIMALS**

Dear Dr. Benz:

The AHVMA is an association of 800+ veterinarians who practice veterinary medicine integratively, making use of conventional, traditional, novel and unproven therapies as warranted by each individual client and patient presented to us. Surgery, pharmaceuticals, acupuncture, spinal manipulation, homeopathy, herbal medicine, physical therapy, nutraceutical and nutritional therapies are all modalities in which we have interest, experience, and often, certification. We (like most other veterinarians) learn and use new techniques to augment what we learned in veterinary school, and have become familiar with their efficacy and safety.

Veterinarians who practice using nutraceuticals and herbal medicine and who teach in this area have gained expertise using products that have been widely available for at least 15 years, if not for centuries, as is the case with herbal medicines. Some of these holistic practitioners work as adjunct specialists with large general and specialty practices. Some are now teaching as part of the curriculum or as continuing education in veterinary schools.

At issue is the current AAFCO (American Association of Feed Control Officials) statement of an intent to more strongly regulate the use of nutraceuticals in the pet industry. While we understand that unapproved supplements labeled for animals have always been illegal, FDA and AAFCO have given these products low regulatory priority for a number of years. In that time, veterinarians and animal owners have to come to regard these products as integral in maintaining the health of companion animals. Enforcement of this policy now will endanger the health of companion animals in a number of ways.

1. As long as human supplements regulated under DSHEA are still available, animal owners will simply switch to these products. Since human supplements are not designed with the variation in animal size or unique physiologic needs in mind, this represents a significant danger to small animals, and a potential waste of money for larger animals. Owners have always bought and administered drugs and supplements for humans, and this practice will increase. Removing supplements labeled for animals from sale will not improve animal safety.

2. Removal of supplements labeled for animals will cut the legs out from under the growing efforts to generate data on these supplements. Most are not patentable, and we depend on ethical supplement companies to fund this research. If they cannot sell products recommended by veterinarians and used safely for years by pet owners, data will NEVER be forthcoming. Since the problem is lack of data, removal of supplements will not solve the problem.

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3. Although this action is reportedly undertaken to assure the safety of companion animals, we would like to see the significant numbers of adverse event reports in animals. We believe that safety data could easily be generated by the veterinarians and owners presently using these supplements, if the protocols were designed and supported by knowledgeable people in industry or government. State feed control officials and the FDA should utilize their limited resources more productively - they need to gather more information from those who have the most experience with these supplements, and help implement a new structure for optimizing patient outcomes and adverse event reporting.

Removal of animal supplements from sale will not solve the problem; indeed, it will significantly worsen the situation. Below are listed some possible solutions:

1. Separate food animal and pet/exotic assessment criteria (even if supplements do present food-chain issues, it is not reasonable to lump food animals together with companion and exotic animals).

2. Create a separate category for regulation.

3. Involve stakeholders before advising enforcement strategies to state feed control officials.

4. Utilize veterinarians as a first line of information gathering for toxicity data—implement existing prescription practices and therapeutic relationships as a structure for studying outcomes and safety data.

We realize that these changes may take an Act of Congress. There will be a public outcry if the FDA and AAFCO continue to encourage this enforcement initiative. The AHVMA encourages AAFCO and FDA to recognize that alternative strategies to improve quality control in dietary supplements will benefit animals more comprehensively. We will support only those regulatory initiatives that preserve effective products on which we depend, while bringing the rest of the industry into line regarding quality assurance and safety considerations.

Sincerely,

Mike Kohn, DVM
AHVMA President-Elect
for the Board of Directors of the AHVMA

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I wasn't sure if you would want to respond or not. It is not UAFed. I was tempted to send it to [illegible]. Where were the before. [illegible]

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